

NEXT GENERATION REGULATORY INFORMATION MANAGEMENT SYSTEM (RIMS)



Industry Need

Regulatory affairs is a critical function for biopharmaceutical organizations to manage, however the complexity of operations often prevents organizations from realizing the benefits of investing in research and new markets. A Regulatory Information Management System (RIMS) should be able to keep up with evolving needs or else, it can result in:

Longer cycle time for document collection and application submission for approvals & filing updates, resulting in delays in patient care and revenue loss



Increased costs of compliance with upcoming mandates like IDMP

Lack of straight-forward reporting capabilities causing blind spots for senior management within pharma organizations



Key Solution Attributes/Tenets

Infosys Regulatory Submission Platform offers next-generation RIMS capability by optimizing the regulatory submissions process to accelerate time-to-market, reduce cycle times with regulators and maximize research investments and value.



RIMS lifecycle process coverage - from product registration to approval tracking



Best-in-class tools seamlessly integrated to provide end-to-end services



Proactive adoption of new regulatory standards, continuous assessment and upgrades



Collaboration with partners through integrated systems and processes



Outcomes

Organizations can expect the below outcomes from the next-generation Infosys RIMS platform:

Reduced product recall risks



Flexibility to support increased activity in new and emerging markets



Reduced approval cycle time by ~15%



Unified landscape - single integration solution for end-to-end Regulatory Information and Submission Management

Improved partner management through externalization